K090371

STERIS®

MAY - 1 2009

510(k) Summary
For
Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System

STERIS Corporation
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Contact: John Robert (Jack) Scoville.
Fellow, Regulatory Affairs
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Summary Date: February 12, 2009

1. Device Name

Trade Name:	Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System
Common/usual Name:	Sterilization pouch
Classification Name:	Sterilization wrap (21 CFR 880.6850 Product Code KCT).

2. Predicate Device

- Vis-U-All Self Seal Pouch (K070765)
- Vis-U-All Heat Seal Pouch and Tubing (K071087)

3. Description of Device

The proposed Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System is a Tyvek/plastic film sterilization containment pouch designed for devices to be sterilized by the health care provider in the Amsco V-PRO 1 Low Temperature Sterilization System. The proposed pouch is available as either a self seal pouch, a heat seal pouch, or heat seal tubing.

The purpose of this submission is to demonstrate the Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System is safe and effective for double pouching.

4. Intended Use

The Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System has been qualified by STERIS Corporation as suitable for use by health care providers to enclose and seal other medical devices to be sterilized in the Amsco V-PRO 1 Low Temperature Sterilization System. The Vis –U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

5. Description of Safety and Substantial Equivalence

The device models are identical to the cleared predicate devices K070765 and K071087.

Testing of the Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System demonstrated that the proposed pouches and tubing are safe and effective when double-pouched.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Mr. John Robert Scoville, Jr.
Fellow, Regulatory Affairs
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K090371
Trade/Device Name: Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-Pro 1 Sterilization System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: March 31, 2009
Received: April 1, 2009

Dear Mr. Scoville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K090371**

Device Name: **Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System**

Indications For Use:

The Vis-U-All Low Temperature Tyvek Sterilization Pouches are sterilization containment pouches for use by the health care providers to enclose medical devices to be sterilized in the Amsco V-PRO 1 Low Temperature Sterilization System. The pouches maintain the sterility of the enclosed device during normal handling and storage until the pouch is opened and the medical device is removed for use.

Type	Size	Type	Size
Pouch, Self Seal and Heat Seal, Tyvek	3" x 7"	Tubing, Heat Seal, Tyvek	3" x 100'
	4" x 9"		4" x 100'
	4" x 12"		6" x 100'
	4" x 22"		9" x 100'
	6" x 10"		14" x 100'
	8" x 12"		
	10" x 15"		
	12" x 18"		

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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